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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,548	07/16/2003	Robert Flower	14398	5957

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EXAMINER	
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ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,548	FLOWER, ROBERT	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed February 23, 2007 have been fully considered but they are not persuasive. The method steps disclosed by Flower et al. and Pang anticipate those of the application. Flower et al. discloses the method steps may have any sequence, while Pang specifically indicates a sequence as cited by the applicant. The argument that neither discloses the same reasoning as the applicant for the steps or their sequence does not alter the clear disclosure of the claimed method steps. Both Flower et al. and Pang teach the photocoagulation of the feeder vessel to reduce the flow of blood. Such flow reduction would inherently reduce the exit of photosensitizer from the target lesion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32 and 37-51 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,976 to Flower et al. Flower et al. teach a method for treating a lesion, such as a CNV or tumor, in an animal. The methods contemplate treating such a lesion by subjecting the lesion to PDT, and subjecting a blood vessel that carries blood into the lesion to thermal photocoagulation to reduce the flow of blood through that vessel and into the lesion (Col. 2, lines 27-35). A fluorescent dye is used to obtain angiograms of the vasculature of interest to permit accurate targeting, while a radiation-absorbing dye is used in dye-enhanced

photocoagulation effect treatment of feeder vessels (Col. 7, lines 1-5). This is the step of locating the feeder vessel. The PDT dyes are disclosed as hematoporphyrins, aminolevulinic acids, porphyrins, merocyanines, porphycenes, porfimer sodium, verteporfin, Photofrin II, PH-10, chlorins, zinc phthalocyanine, purpurins, pheophorbides and monoclonal antibody-dye conjugates of any of the foregoing dyes (abstract). The treatment step of thermal photocoagulation is preferably performed after the application of PDT when reperfusion of the CNV is detected, but the inventive methods are not limited to that sequence (Col. 6, lines 22-26). Flower et al. teach that the methods and associated steps may be performed in any logical order (Col. 3,lines 36-37). The photocoagulation radiation-absorbing dyes are disclosed as fluorescein, rose bengal and indocyanine green (Col. 7, lines 31-35). Flower et al. teach a relationship between the type of photodynamic dye, the formulation, mode of administration, and dosage level, adjustment of these parameters to fit the particular combination to ensure delivery of an effective amount of the dye formulation to the targeted tissue is possible. (Col. 5, lines 20-26). This implies delivery over a set period of time based on the parameters. The delivery of dyes via liposomes is disclosed as being well known in the art (Col. 8, lines 11-16), and this is interpreted to include the various properties associated therewith. Flower et al. teach the radiation-absorbing dyes may also fluoresce, permitting the same dye to be used to obtain angiographic images of blood vessels, and treatment of vessels targeted as a result of the angiogram (Col. 7, lines 25-30), thus being used to confirm a target has "filled" with a treatment composition. Flower et al. teaches the use of angiographics at various stages of the treatment of vessels. The applicant cites the same steps for determining the rate the composition exits the lesion as for the other visualizations. It is implicit the angiographic images of Flower et al. can be used for this purpose.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-34 and 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/47107 to Pang et al. in view of U.S. Patent 6,443,976 to Flower et al. Pang teaches a method for treating neovascularization of an eye where a feeder blood vessel is located using fluorescent imaging and confirming the locations (page 19, line 5), then using a laser to burn the feeder (page 20, line 30), confirming the feeder vessel is blocked by injecting indocyanine green (ICG) and confirming the vessel does not "fill" (page 21, line 2) and then using photodynamic therapy to treat the target where the photosensitizer has selectively been absorbed and irradiating the target with a frequency of the sensitizers wavelength. The confirmation of the blocking of the feeder vessel is interpreted as an alternative equivalent of confirming the exit rate of sensitizer from the target tissue as both serve the purpose of confirming the feeder is blocked. ICG is also disclosed as working as a photosensitizer (Page 21, lines 33-37) thus establishing is use as both a fluorescing agent and sensitizing agent. The ICG may be administered as a bolus (page 19, line 31). Pang teaches the time required for a dye to reach an eye is 10 to 25 seconds and then the image capture sequence begins, thus teaching a pre-defined time interval (page 15, line 35). The feeder identification uses the dye with illumination and image capture to positively locate the feeder vessel (page 14-16). Pang et al. do not disclose additional photodynamic agents. Flower et al. are discussed above and teach the use of hematoporphyrins, aminolevulinic acids, porphyrins, merocyanines, porphycenes, porfimer sodium, verteporfin, Photofrin II, PH-10, chlorins, zinc phthalocyanine, purpurins, pheophorbides

and monoclonal antibody-dye conjugates of any of the foregoing dyes as PDT agents. It would have been obvious to one skilled in the art to use the alternative photosensitizers as taught by Flower et al. in the method of Pang et al., as a skilled artesian would know the many photosensitizers and would be motivated to look to other disclosed methods for treating AMD. Minor alterations in the methods that do not result in unexpected advances in the treatment efficacies are obvious to one skilled in the art.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,443,976 to Flower et al. as applied to claim 32 above and further in view of U.S. Patent 6,351,663 to Flower et al. Flower et al. '976 is discussed above, but does not disclose administration of the composition as a rapid bolus or a saline flush. Flower et al. '663 teach the introduction a liquid composition for CNV treatment as boluses comprising a fluorescent dye (Col. 4, line 17), the bolus may be followed by the administration of a saline flush (Col. 4, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to introduce the dye as a bolus, followed by a saline flush as taught by Flower et al. '663 in the method of Flower et al. '976 as an alternative equivalent means of introduction.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

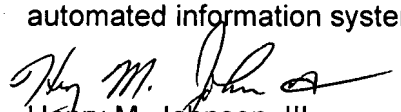
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Henry M. Johnson, III
Primary Examiner
Art Unit 3739